CITMA
COALITION OF INDEPENDENT TOBACCO MANUFACTURERS OF AMERICA

November 9, 2015

Via Overnight Delivery & Electronic Mail

Mitch Zeller, J.D.
Director
Center for Tobacco Products
Document Control Center (DCC)
9200 Corporate Blvd.
Room 020J
Rockville, MD 20850

Re: Apparent Leak of Deeming Regulation Documents

Dear Director Zeller:

On behalf of the Coalition of Independent Tobacco Manufacturers of America (CITMA), we express our members' grave concerns about the regulatory process used by the U.S. Food and Drug Administration (FDA) for exercising its so-called "deeming" authority to subject additional tobacco products to the controls of Chapter IX of the Federal Food, Drug, and Cosmetic Act. For the second time, it appears that the Tobacco Vapor Electronic Cigarette Association (TVECA), and through TVECA perhaps others, obtained a draft version of FDA's rule (and a related guidance document) prior to its official publication in the Federal Register. This *ex parte* communication with a small segment of the industry is procedurally infirm, contrary to law, and fundamentally unfair. In order to ensure a level playing field and cure the prejudice to other stakeholders, we hereby request that FDA immediately release to the public a copy of all leaked materials in the possession of TVECA. In the alternative, if FDA cannot determine which versions of which deeming documents TVECA possesses, we request that FDA release the draft version of the final deeming regulation transmitted to the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget.

FDA acknowledged the most recent apparent leak of its final deeming regulation[1] and the *ex parte* communications in which it engaged with TVECA regarding the matter. Significantly, this is the second reported leak to TVECA in this rulemaking process. In April 2014, FDA

[1] FDA, A Special Statement from CTP (Oct. 31, 2015), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm470409.htm.

acknowledged TVECA's claim that it had a copy of the proposed deeming regulation prior to publication.[2] At that time, counsel for CITMA spoke with the Center for Tobacco Products Ombudsman and requested an investigation of the apparent leak. To our knowledge, FDA never confirmed publicly that it conducted any investigation or took any other action in response to our request.[3] Now the situation has recurred at an even more critical juncture in the rulemaking process. It is deeply troubling that the Agency lacks transparency in this matter and that TVECA and perhaps others again appear to have obtained a draft version of the rule prior to its official publication.

We note that, in the event of prohibited *ex parte* communications in the rulemaking process, courts have required the withdrawal of the rule and further rulemaking activies.[4] This is especially true where the release of information violates the Agency's own rulemaking procedures. *See* 21 C.F.R. § 10.80(d)(2) (providing that a "draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the Federal Register").

Ex parte release of the final rule (and at least one companion guidance document) prior to publication, even if additional changes may be requested by OIRA, places all other stakeholders, including CITMA's small business members, at a significant competitive disadvantage. First, those with access to the full content of the regulations and related documents have effectively received advance notice of, and thus more time to comply with, the requirements set forth in the regulations relative to members of industry who must wait for the documents' official publication. For example, these noticed companies can conduct business and compliance planning activities to prepare for implementation of the rule. Second, those with access to the draft final rule can engage more effectively with OIRA, and other agencies participating in the OIRA review, to advance their agendas. Thus, in order to ensure a fair process and restore a level playing field, FDA must immediately grant the relief requested.

We additionally request that FDA conduct full investigations of both of these apparent leaks and publicly report the results. These events have shaken our confidence in the integrity and fairness of the deeming process and FDA's internal procedures. Thorough transparent investigations, as well the implementation of measures to address the apparent weaknesses in

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[2] FDA, A Special Statement from CTP (Apr. 18, 2014), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm394018.htm.

[3] On October 29, 2015, CITMA filed a request under the Freedom of Information Act seeking all documentation regarding FDA's April 2014 investigation, if any, but has not yet received a response.

[4] *E.g., Sangamon Valley Television Corp. v. United States*, 269 F.2d 221 (D.C. Cir. 1959) (invalidating a Federal Communications Commission (FCC) rule regarding television channel allocations where it was FCC practice to provide a cut off for comments and forbid the filing of additional comments unless requested by the Commission, but a commenter met with each Commissioner individually after that date).

FDA's internal document control processes, could help mitigate the damage done to date and improve public confidence in the integrity and fairness of FDA's regulatory activities.

Thank you for your consideration. We look forward to hearing from you.

Sincerely,

Kevin Altman /so/

Kevin Altman
Consultant, CITMA

cc: Ella Yeargin, CTP Ombudsman
Lindsay Tobias, Office of Policy
Elizabeth H. Dickinson, Chief Counsel

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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Kevin Altman
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NOV 2 5 2015

Dear Mr. Altman:

Thank you for your November 9, 2015 letter regarding concerns the Coalition of Independent Tobacco Manufacturers of America (CITMA) has with the recent allegations made by the Tobacco Vapor Electronic Cigarette Association (TVECA) about FDA's final tobacco "deeming" rule and a related guidance document.

The FDA has not yet issued its final rule and other documents related to extending the agency's authority to other currently unregulated tobacco products. We are aware that the Tobacco Vapor Electronic Cigarette Association (TVECA) has indicated publicly that it has a copy of the draft final rule. We cannot confirm if TVECA has a copy of the most recent version of the draft final rule, or even if their copy is authentic. It is our understanding based on recent conversations between the FDA and TVECA, that the group will not be releasing the document in question.

FDA is concerned about any unauthorized release of non-public documents still under review. As a matter of policy, the FDA does not share draft documents or negotiate with outside groups while they are under review. The FDA is committed to maintaining the integrity of the regulatory process. It is important to note that the rule is still in draft form and was submitted to the Office of Management and Budget (OMB) on October 19, 2015. OMB is required to review all significant regulatory actions.

The FDA remains committed to an open dialogue with all interested parties, including industry, consumers and the public health community – and looks forward to the completion of this important rulemaking.

Thank you for contacting FDA concerning this matter.

Sincerely,

Mitchell Zeller

Mitchell Zeller
Director, Center for Tobacco Products

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

en Español (http://esp.fda.gov/TobaccoProducts/default.htm)

A Special Statement from CTP - October 31, 2015

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Smokers deserve lower-risk alternatives to the deadly cigarette

By Michael Siegel and Scott D. Ballin

When the Tobacco Control Act was enacted in 2009, it established a predicate date of February 15, 2007 for products subject to the Act: namely, cigarettes and smokeless tobacco. While any new brands introduced to the market would have to file complex and burdensome applications with the Food and Drug Administration (FDA) for pre-approval, all existing cigarette brands—which includes every cigarette currently on the market—were given a free ride. This means that every cigarette brand on the market is allowed to continue being sold, without any changes in nicotine content, without eliminating menthol—which is known to appeal to youth—and without lowering the levels of any of the more than 60 known carcinogens in these products.

Therefore, it may come as a surprise to many to find out that despite the lack of any safety regulations for deadly cigarettes, the FDA has sent for executive branch approval a set of regulations for electronic cigarettes—devices that contain no tobacco, involve no combustion, and have been shown to be orders of magnitude safer than cigarettes—that require every electronic cigarette product to submit burdensome, expensive, and technically near-impossible applications just to stay on the market.

The FDA has apparently decided that electronic cigarettes pose a much greater threat to the health of the public than the extremely toxic tobacco cigarettes that are killing more than 400,000 Americans each year. While tobacco cigarettes are given a free ride – they can stay on the market without submitting any application and without satisfying any safety requirement—much safer electronic cigarettes must go through a nearly impossible, expensive, and burdensome application process that will decimate the industry.

In 2007, e-cigarettes were in their infancy and it was unclear as to how they would be regulated. Over the last couple of years that has changed. Thus, as the FDA moves to regulate e-cigarettes, it should establish a predicate date based upon the date when FDA's deeming regulations go into effect, rather than trying to rely on a date that is close to eight years old and which would give the cigarette market a decisive advantage.

In terms of science and technological advancement, today's products are light years ahead of what was on the market in 2007. As one major tobacco control organization has stated, we should be seeking to 'maximize e-cigarette benefits and minimizing their potential harms.' Why should the most toxic consumer products on the market—combustible cigarettes—have to do absolutely nothing to stay on the market, while much safer, tobacco-free electronic cigarettes have to file burdensome and prohibitively expensive applications?

It seems that the issue of 'descriptive flavors' targeted at 'children' is the clarion call from anti-smoking groups like the Campaign for Tobacco-Free Kids for the use of the 2007 date, and it's an easy argument for members of Congress to latch on to.

But the anti-smoking groups' views are short-sighted. Preventing e-cigarettes from competing with real cigarettes is the best possible outcome for continued high rates of cigarette sales. By taking e-cigarettes off the market, the cigarette industry will enjoy an unfettered profit stream via the elimination of any serious competition. And changing the predicate date for e-cigarettes would not in any way inhibit the FDA's oversight of candy-flavored e-cigarettes. The agency is free, at any time, to promulgate safety standards for all electronic cigarettes, something that it has—ironically—not done for tobacco cigarettes.

We believe that the FDA deeming regulations should be the focal point for directly dealing with e-cigarette safety issues by establishing product standards, labeling and marketing controls, and restrictions on flavorings such as diacetyl, that are known to be toxic to humans. Using the 2007 predicate date would result in the removal of at least 99 percent of electronic cigarettes from the market, turning back the clock on all of the technological advancements that have taken place. Such an approach protects the cigarette industry while stifling companies willing to invest in products that could have a significant impact on the health of this nation.

We have spent decades working on tobacco-related issues in the advancement of public health, including working with members of Congress on FDA oversight of tobacco products. We believe that the federal government needs a more rational approach to the regulation of tobacco and nicotine products that regulates all products based on their risks and relative risks. Protecting the cigarette industry while stifling innovation of new and much safer products does not achieve that goal and will damage public health efforts.

Siegel is a professor in the Department of Community Health Sciences, Boston University School of Public Health. Ballin is a health policy consultant and former vice president and legislative counsel for the American Heart Association. Both are 30-year veterans of the tobacco control movement.

http://thehill.com/blogs/congress-blog/healthcare/261323-smokers-deserve-lower-risk-alternatives-to-the-deadly